

Remarks

In the Office Action dated December 17, 2004, claims 30-35, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 30-35 are under consideration and claims 36-39 have been withdrawn.

Claim 34 was objected to as being of improper dependent form. Claim 34 has been amended to delete the limitation that the antibody or antibody fragment has a binding specificity to the epitope 52-60 of uPAR. In view of this amendment applicants request that this objection be withdrawn.

Claims 34-35 were rejected under 35 USC §112, first paragraph, as lacking enablement. Claim 34 has been amended to indicate that the antibody or antigen binding fragments have the same binding specificity as monoclonal antibody IIIF10. Applicants respectfully contend that the CDR sequences in the present application enable one skilled in the art to make such an antibody. In view of this amendment applicants request that this rejection be withdrawn.

Claims 34-35 were rejected under 35 USC §112, first paragraph, as lacking an adequate written description. The office action indicates that it is unclear as to whether the uPAR is human UPAR. Applicants respectfully point out that claim 34 depends from claim 30 which clearly indicates that the uPAR is human uPAR. In view of this, applicants request that this rejection be withdrawn.

Claim 35 was rejected under 35 USC §112, first paragraph, as lacking enablement. Claim 35 has been amended to recite the CDR1 and CDR2 regions

of the H- and L chain. These amendments are supported by the disclosure on page 11, lines 1-12, of the present application. In view of these amendments, applicants request that this rejection be withdrawn.

Claims 30-35 were rejected under 35 USC §103(a) as unpatentable over Dano in view of Luther and Heiss and Terstappen. Applicants respectfully point out that though the IIIF10 antibody was disclosed in Luther, Luther does not suggest or disclose that the IIIF10 antibody can discriminate cancer cells from normal cells. The present claims are method claims for the diagnosis of tumors. Though Luther's antibody may inherently bind to the recited epitope, there is no suggestion in Luther that his antibody or any antibody which binds to the epitope 52-60 of human uPAR can be used to diagnose tumors. In fact, none of the cited references suggest or disclose that an antibody which binds to the epitope 52-60 of human uPAR can be used to diagnose tumors. Applicants respectfully contend that Luther's antibody may inherently bind to the recited epitope but one skilled in the art would not reasonably have expected Luther's antibody to be useful for differentiating between tumor and normal cells based on the disclosure in Dano, Heiss, Luther and Terstappen. Dano's antibody detects and quantifies u-PAR but does not discriminate between tumor u-PAR and normal u-PAR. Dano states at col. 14, lines 31-33 that it "may even be so that some cells, e.g. cancer cells, have substantially different u-PARs which might have important therapeutic significance...". Thus, Dano did not even conclusively know that tumor and normal uPARs were different and could be discriminated using only one antibody. Terstappen does not cure this deficiency as Terstappen only

teaches a method for diagnosing and monitoring leukemia using antibodies with different labels. Terstappen does not suggest that tumor u-PAR and normal u-PAR can be discriminated or what epitope can be used to discriminate them. Heiss does not cure the deficiencies in the other cited references as Heiss detects uPAR from tumor cells but does not indicate that tumor and normal uPAR can be differentiated. Since none of the cited references suggest or disclose that tumor and normal uPAR can be differentiated using antibodies which bind to epitope 52-60 of human uPAR, the presently claimed method using such antibodies to diagnose tumors would not have been obvious. Claim 30 has been amended to more clearly indicate that the antibody differentiates normal and tumor uPAR. In view of these amendments and the above comments, applicants request that this rejection be withdrawn.

Claims 34-35 were rejected under 35 USC §112, second paragraph, as indefinite. Claim 34 has been amended to indicate that the antibody or antigen binding fragment thereof has the same binding specificity as monoclonal antibody IIIF10. In addition, since claim 34 depends from claim 30, it is clear that the uPAR is human uPAR. In view of these amendments, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 30-35 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By



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